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10/025,191	12/18/2001	William F. Avrin	MED/US-11	8506

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EXAMINER	
ROY, BAISAKHI	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/025,191	AVRIN ET AL.
	Examiner	Art Unit
	Baisakhi Roy	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 18 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/10/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (5494033) in view of Ketchen (4588947).

Regarding claims 1-3, Buchanan et al. discloses a source-sensor unit for a magnetic susceptibility measuring instrument comprising of a field generating element and a magnetic sensor (abstract, col. 2 lines 38-62, col. 4 lines 21-35, and claim 1) but, does not explicitly disclose the arrangement of the field generating element and the magnetic sensor to be such that the signal due to the applied field is cancelled and where said cancellation is preserved. Ketchen discloses a magnetic susceptibility measuring instrument with a field generating element such as a field coil and a detector element such as sensor coils symmetrically arranged between said field coils such that the signal due to the applied field is canceled out and said cancellation is preserved (abstract, col. 5 lines 22-30, col. 6 lines 6-15 lines 65-68, and claims 1-18). Ketchen further teaches said system to include the field coil centered between the two co-axially wound sensor coils which are connected in series (col. 4 lines 18-21 lines 27-30 lines 64-68, and col. 5 lines 66-68). It would have therefore been obvious to one of ordinary skill in the art to use the symmetrical source-sensor unit arrangement teaching by

Ketchen in the teaching by Buchanan et al. for the purpose of canceling out the signal due to the applied field coil and preserving said cancellation as the unit expands and contracts uniformly.

Regarding claims 4-8, Buchanan et al. teaches said source-sensor unit to include thermally insulating enclosure, a heat sink placed symmetrically with respect to the plane of symmetry of said source-sensor unit and outside of the thermally insulating enclosure, thermally conductive links connecting the coil form to said heat sink, and placing said coil form next to a large solid thermal mass (abstract, col. 2 lines 42-51 lines 63-67, col. 3 lines 30-40, col. 4 lines 62-67, col. 6 lines 52-67, col. 7 lines 1-6, col. 8 lines 59-67, col. 9 lines 1-4, and claim 1).

3. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, as set forth above, and further in view of McCormick (4431005). Buchanan et al. and Ketchen does not disclose said coil form to be constructed as a thick-walled hollow cylinder. McCormick discloses a magnetic susceptibility measuring instrument to be composed of coils that are co-axially wound and disposed inside a solid hollow cylindrical casing (col. 2 lines 50-53, col. 6 lines 65-68, and claims 1-6). It would have therefore been obvious to one of ordinary skill in the art to use the cylindrical coil form teaching by McCormick in the teaching by Buchanan et al. and Ketchen for the purpose of providing a large thermal mass.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, as set forth above, and further in view of Hirschkoff (5081071). Buchanan et al. and Ketchen discloses a source-sensor unit for a magnetic

susceptibility measuring instrument comprising of a field generating element and a magnetic sensor with said sensor placed in between the field generating element but does not explicitly disclose the field generating element to be composed of plurality of applied-field coils. Hirschkoff discloses a system for taking magnetic susceptibility measurements with sensors and a field-generating element comprised of a plurality of field coils and which cancel each other to create a region of zero magnetic field (abstract, col. 5 lines 34-61, col. 6 lines 6-10, col. 10 lines 49-68, and col. 11 lines 1-12 lines 58-63). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Hirschkoff regarding the plurality of field coils in the teaching by Buchanan et al. and Ketchen for the purpose of generating magnetic fields which cancel each other in a region between the plurality of field coils and said sensor is placed in said region of zero magnetic field.

5. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, in view of Hirschkoff, as set forth above, and further in view of Visioli, Jr. (4042876). Buchanan et al, Ketchen, and Hirschkoff as described above discloses said sensor to be positioned between the circuitry network in said region of zero magnetic field and composed of materials having similar thermal expansion coefficients but does not explicitly disclose any components or details pertaining to the printed circuit boards. Visioli, Jr. discloses a detection system comprising of a printed circuit board with a number of parallel, evenly spaced traces and connected in series with said board composed of identical layers of metal on both sides with the trace formed of copper (abstract, fig. 4/5, col. 2 lines 29-45, col. 3 lines 21-35,

col. 4 lines 39-44). It would have therefore been obvious to one of ordinary skill in the art to use the printed circuit board teaching by Visioli, Jr. in the teaching by Buchanan et al., Ketchen, and Hirschkoff for the purpose of using creating carrying the metallic coil pattern and enabling the unit to maintain symmetry and cancellation of the applied field.

6. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, in view of Hirschkoff, in view of Visioli, Jr. as set forth above, and further in view of Ammon et al. (3660726). Buchanan et al., Ketchen, Hirschkoff, and Visioli, Jr. does not explicitly teach said printed circuit board as described above to be composed of G-10 fiberglass. Ammon et al. discloses a multi-layered printed circuit board pattern to be composed of G-10 fiberglass (abstract, col. 2 lines 24-38). It would have therefore been obvious to one of ordinary skill in the art to use the G-10 fiberglass teaching by Ammon et al. in the teaching by Buchanan et al., Ketchen, Hirschkoff, and Visioli, Jr. for the purpose of generating a good match of thermal expansion coefficients between the copper coils as described above and the supporting structure.

7. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, in view of Hirschkoff, in view of Visioli, Jr., as set forth above, and further in view of Lindner et al. (5172472). Buchanan et al., Ketchen, Hirschkoff, and Visioli, Jr. does not explicitly teach said printed circuit board as described above to be composed of FR-4 fiberglass. Lindner et al. discloses a multi-layered printed circuit board pattern to be composed of FR-4 fiberglass (col. 3 lines 32-

58). It would have therefore been obvious to one of ordinary skill in the art to use the FR-4 fiberglass teaching by Lindner et al. in the teaching by Buchanan et al., Ketchen, Hirschkoff, and Visioli, Jr. for the purpose of generating a good match of thermal expansion coefficients between the copper coils as described above and the supporting structure.

8. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. in view of Ketchen, as set forth above, and further in view of Paulson (4827217). Buchanan et al. and Ketchen teaches said source-sensor unit comprising of structures defining the shapes, dimensions, and geometrical relationships of the field generating element and magnetic sensor with said structures being constructed of materials with low thermal expansion coefficients and with said coil form winding the field and sensor coil structures (abstract, col. 2 lines 21-62, col. 4 lines 15-35, col. 7 lines 14-18, col. 9 lines 5-8, and claim 1) but, does not disclose the low thermal expansion structure of be composed of a material selected from the group listed in claim 19. Paulson discloses an instrument for conducting magnetic susceptibility measurements with a source-sensor unit apparatus composed of quartz material (abstract, col. 8 lines 9-26). It would have therefore been obvious to one of ordinary skill in the art to use the quartz material teaching by Paulson in the teaching by Buchanan et al. and Ketchen for the purpose of minimizing thermal drifts in the geometry of the unit.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. (5494035) in view of Buchanan et al. and further in view of Ketchen. Leuthold et

al. discloses a method for performing pre-MRI screening by generating an applied magnetic field in a region of interest and generating magnetic susceptibility measurements relevant to the presence or absence of a ferromagnetic foreign body in said region of interest (abstract, col. 2 lines 13-34, col. 3 lines 1-8 lines 25-31, and claims 1-12). Leuthold et al. discloses said method to be executed by an instrument with a field generating element and detector elements (col. 2 lines 45-67) but does not explicitly disclose said system to be composed of materials with low thermal expansion coefficients. Buchanan et al. discloses a method for taking magnetic susceptibility measurements with a field generating element and a sensor and constructing the structures which define the shapes, dimensions, and geometrical relationships of said instrument of materials with low thermal expansion coefficients (abstract, col. 2 lines 21-62, col. 4 lines 15-35, col. 7 lines 14-18, col. 9 lines 5-8, and claim 1). It would have therefore been obvious to one of ordinary skill in the art to use the low thermal expansion material teaching by Buchanan et al. in the teaching by Leuthold et al. for the purpose of minimizing thermal drifts in the geometry of the source-sensor unit. Leuthold et al. and Buchanan et al. does not disclose a method involving canceling and preserving the signal due to the applied field by arrangement of the field generating element and sensor and preserving said cancellation as the system expands and contracts uniformly. In the same field of endeavor, Ketchen discloses a system for taking magnetic susceptibility measurements with a field generating element and a detector element symmetrically arranged such that the signal due to the applied field is canceled out and said cancellation is preserved (abstract, col. 5 lines 22-30, col. 6 lines

6-15 lines 65-68, and claims 1-18). It would have therefore been obvious to one of ordinary skill in the art to use the symmetrical source-sensor unit arrangement teaching by Ketchen in the teaching by Leuthold et al. and Buchanan et al. for the purpose of canceling out the signal due to the applied field coil and preserving said cancellation as the unit expands and contracts uniformly.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Buchanan et al. in view of Ketchen as set forth above, and further in view of Paulson. Leuthold et al. Buchanan et al. and Ketchen teaches said source-sensor unit comprising of structures defining the shapes, dimensions, and geometrical relationships of said instrument with said structures being constructed of materials with low thermal expansion coefficients (abstract, col. 2 lines 21-62, col. 4 lines 15-35, col. 7 lines 14-18, col. 9 lines 5-8, and claim 1) but does not disclose the low thermal expansion structure of the instrument to be composed of a material selected from the group listed in claim 22. Paulson discloses an instrument and method for conducting magnetic susceptibility measurements with a source-sensor unit apparatus composed of quartz material (abstract, col. 8 lines 9-26). It would have therefore been obvious to one of ordinary skill in the art to use the quartz material apparatus teaching by Paulson in the teaching by Leuthold et al., Buchanan et al. and Ketchen for the purpose of minimizing thermal drifts in the geometry of the unit.

11. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen. Leuthold et al. discloses a method for performing pre-MRI screening for ferromagnetic foreign bodies by generating an applied

magnetic field in a region of interest and generating magnetic susceptibility measurements relevant to the presence or absence of a ferromagnetic foreign body in said region of interest (abstract, col. 2 lines 13-34, col. 3 lines 1-8 lines 25-31, and claims 1-12). Leuthold et al. discloses said method to be executed by an instrument with a field generating element and detector elements (col. 2 lines 45-67) but does not explicitly disclose said method to involve canceling and preserving the signal due to the applied field by arrangement of the field generating element and sensor and preserving said cancellation as the system expands and contracts uniformly. Ketchen discloses a system for taking magnetic susceptibility measurements with a field generating element and a detector element symmetrically arranged such that the signal due to the applied field is canceled out and said cancellation is preserved (abstract, col. 5 lines 22-30, col. 6 lines 6-15 lines 65-68, and claims 1-18). It would have therefore been obvious to one of ordinary skill in the art to use the symmetrical source-sensor unit arrangement teaching by Ketchen in the teaching by Leuthold et al. for the purpose of canceling out the signal due to the applied field coil and preserving said cancellation as the unit expands and contracts uniformly.

12. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Buchanan et al. Leuthold et al. and Ketchen does not explicitly disclose said method to involve shielding the source-sensor unit, method to remove heat produced by said field coils via the thermal link, controlling the temperature to minimize temperature fluctuations of said unit, placing said thermal link in contact with a large thermal mass, and placing said

thermal link in thermal contact with a temperature stabilizing system. Buchanan et al. discloses a source-sensor unit to take magnetic susceptibility measurements to include a thermally insulating enclosure, a heat sink placed symmetrically with respect to the plane of symmetry of said source-sensor unit and outside of the thermally insulating enclosure, and thermally conductive links connecting the coil form to said heat sink and in contact with a large thermal mass and a temperature stabilizing system (abstract, col. 2 lines 42-51 lines 63-67, col. 3 lines 30-40, col. 4 lines 62-67, col. 6 lines 52-67, col. 7 lines 1-6, col. 8 lines 59-67, col. 9 lines 1-4, and claim 1). It would have therefore been obvious to one of ordinary skill in the art to use the temperature stabilizing system teaching by Buchanan et al. in the teaching by Leuthold et al. and Ketchen for the purpose of insulating the unit and shielding from temperature variations.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen in view of Buchanan et al. as set forth above, and further in view of Paulson. Leuthold et al., Ketchen, and Buchanan et al. includes a temperature stabilizing system as described above but does not explicitly disclose said method to include a temperature stabilizing substance from the list in claim 29. Paulson discloses an instrument and method for conducting magnetic susceptibility measurements using coil and sensor structures and a temperature stabilizing system to be composed of any substance that is able to maintain reduced, constant operating temperatures such as ice in water (col. 4 lines 66-68, col. 5 lines 10-11). It would have therefore been obvious to one of ordinary skill in the art to use the temperature stabilizing substance teaching by

Paulson in the teaching by Leuthold et al., Ketchen, and Buchanan et al. for the purpose of enhancing temperature stability.

14. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Ness (3656481). Leuthold et al. and Ketchen discloses a method for detecting ferromagnetic foreign bodies from various regions of interest and obtaining magnetic susceptibility measurements as described above but does not explicitly state said region of interest to involve the eyes. Ness discloses a method for detecting magnetically attractable objects from the eyeball by rotating the eye in a controlled manner (abstract, col. 1 lines 56-59, col. 4 lines 40-53). It would have therefore been obvious to one of ordinary skill in the art to use the magnetic ophthalmic teaching by Ness in the teaching by Leuthold et al. and Ketchen for the purpose of employing eye movement to locate the ferromagnetic foreign body located within the eye with the changing orientation or position modulating the magnetic susceptibility signal from the ferromagnetic foreign body without changing the magnetic susceptibility response of the patient's body tissues.

15. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Paulson. Leuthold et al. and Ketchen does not explicitly disclose said unit to be composed of a bag of deformable material with a fixed barrier placed next to the region of interest. Paulson discloses a magnetic susceptibility measuring instrument as described above with a source-sensor unit with placement of a bag of deformable water

material next to a body surface of the patient adjacent said region of interest and the placement of a rigid, fixed barrier in contact with said deformable bag (col. 5 lines 46-68, col. 6 lines 1-22). It would have therefore been obvious to one of ordinary skill in the art to use the deformable water bag with rigid barrier teaching by Paulson in the teaching by Leuthold et al. and Ketchen for the purpose of enhancing sensitivity by replacing the varying shapes of the body surface with an air/deformable-material interface of constant shape defined by said barrier.

16. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Sloane (5619991). Leuthold et al. and Ketchen discloses the method of generating and interpreting measurements from said units located at remote locations to be processed by a central computer processing station (col. 2 lines 56-67) but does not disclose said processing station to involve a communication system such as the Internet. Sloane discloses a method of transmitting medical data, measurements, and images to a computer processing station via the Internet and providing real-time interactive feedback mechanism (abstract, col. 1 lines 47-67, col. 2 lines 1-8 lines 62-67, col. 8 lines 48-51). It would have therefore been obvious to one of ordinary skill in the art to use the real-time Internet based telemedicine method teaching by Sloane in the teaching by Leuthold et al. and Ketchen for the purpose of centralizing the computer equipment and enabling enhanced measurements widely available and facilitating quality control in the interpretation of the test results.

17. Claims 34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Gould (5546943). Leuthold et al. and Ketchen discloses the method of generating and interpreting measurements from said units located at remote locations to be processed by a central computer processing station as described above but does not disclose said processing station to involve performing instantaneous autointerpretation of the magnetic susceptibility measurements using artificial intelligence. Gould discloses a method for performing instantaneous autointerpretation of medical images and measurements using artificial intelligence with a real-time interactive feedback mechanism (abstract, claims 1-16). It would have therefore been obvious to one of ordinary skill in the art to use the real-time artificial intelligence based teaching by Gould in the teaching by Leuthold et al. and Ketchen for the purpose of providing instantaneous autointerpretation of test results.

18. Claims 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leuthold et al. in view of Ketchen as set forth above, and further in view of Kiyuana et al. (5524086). Leuthold et al. and Ketchen discloses the method of generating and interpreting measurements from said units located at remote locations to be processed by a central computer processing station as described above but does not disclose said processing station to involve performing instantaneous autointerpretation of the magnetic susceptibility measurements using a neural network. Kiyuna et al. discloses a method of performing instantaneous autointerpretation of magnetic susceptibility measurements using a neural network (abstract, col. 2 lines 1-8 and claim 1). It would

have therefore been obvious to one of ordinary skill in the art to use the neural network based teaching by Kiyuna et al. in the teaching by Leuthold et al. and Ketchen for the purpose of providing instantaneous autointerpretation of test results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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